Intercambialidade

IEDA LAURINDO

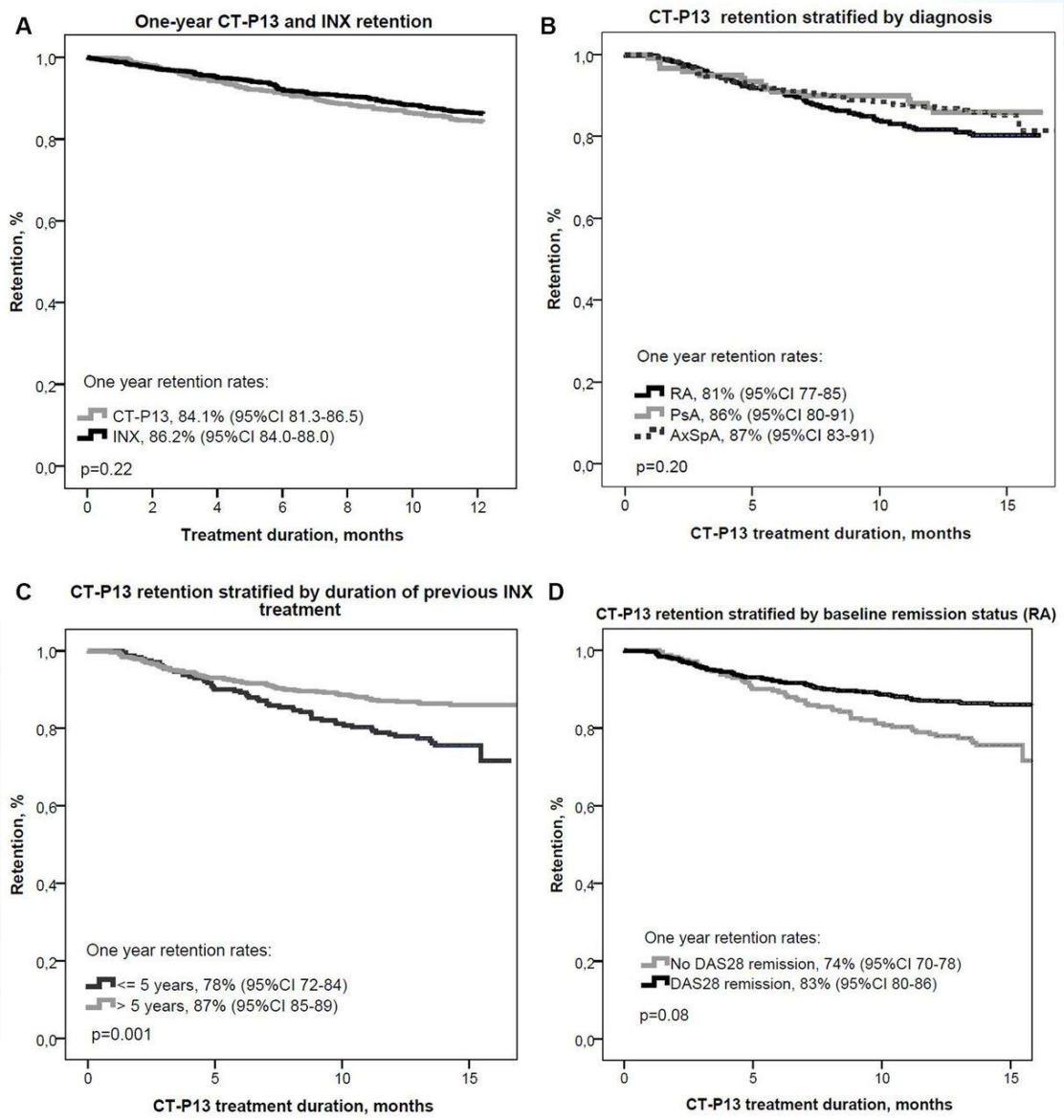
SOCIEDADE BRASILEIRA DE REUMATOLOGIA

No momento,

1) Sociedade elabora sua posição official
   a) promoção de um forum de debates em julho de 2017;
   b) ampla discussão entre diferentes setores e comissões

No momento,

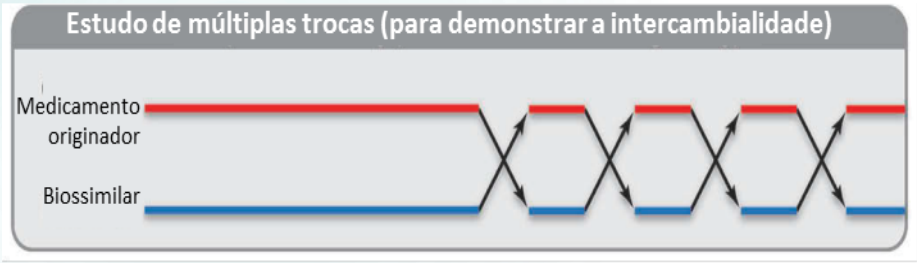
2) considerando: definição de biossimilares

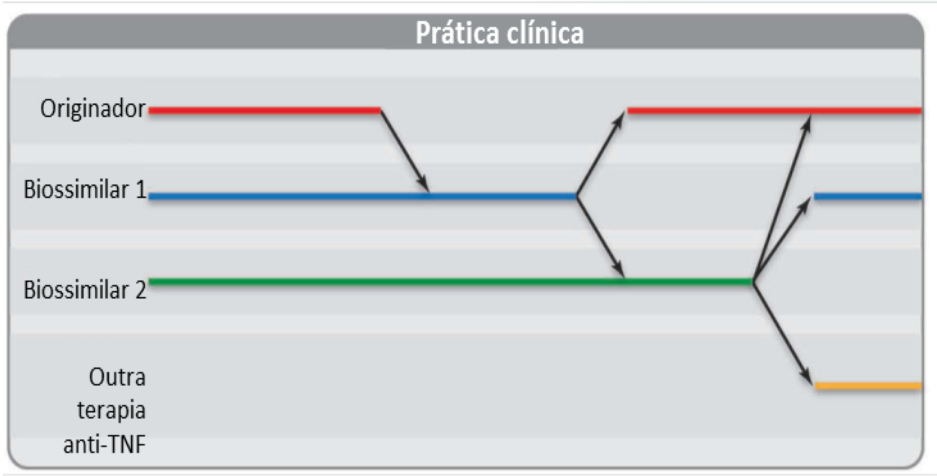


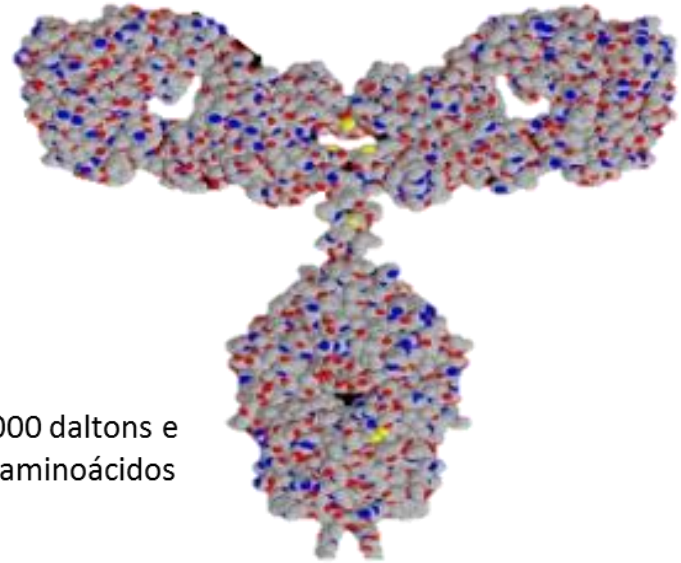
Glintborg B, sørensen iJ, Loft AG, et al. Ann Rheum Dis 2017;76:1426–1431.

No momento,

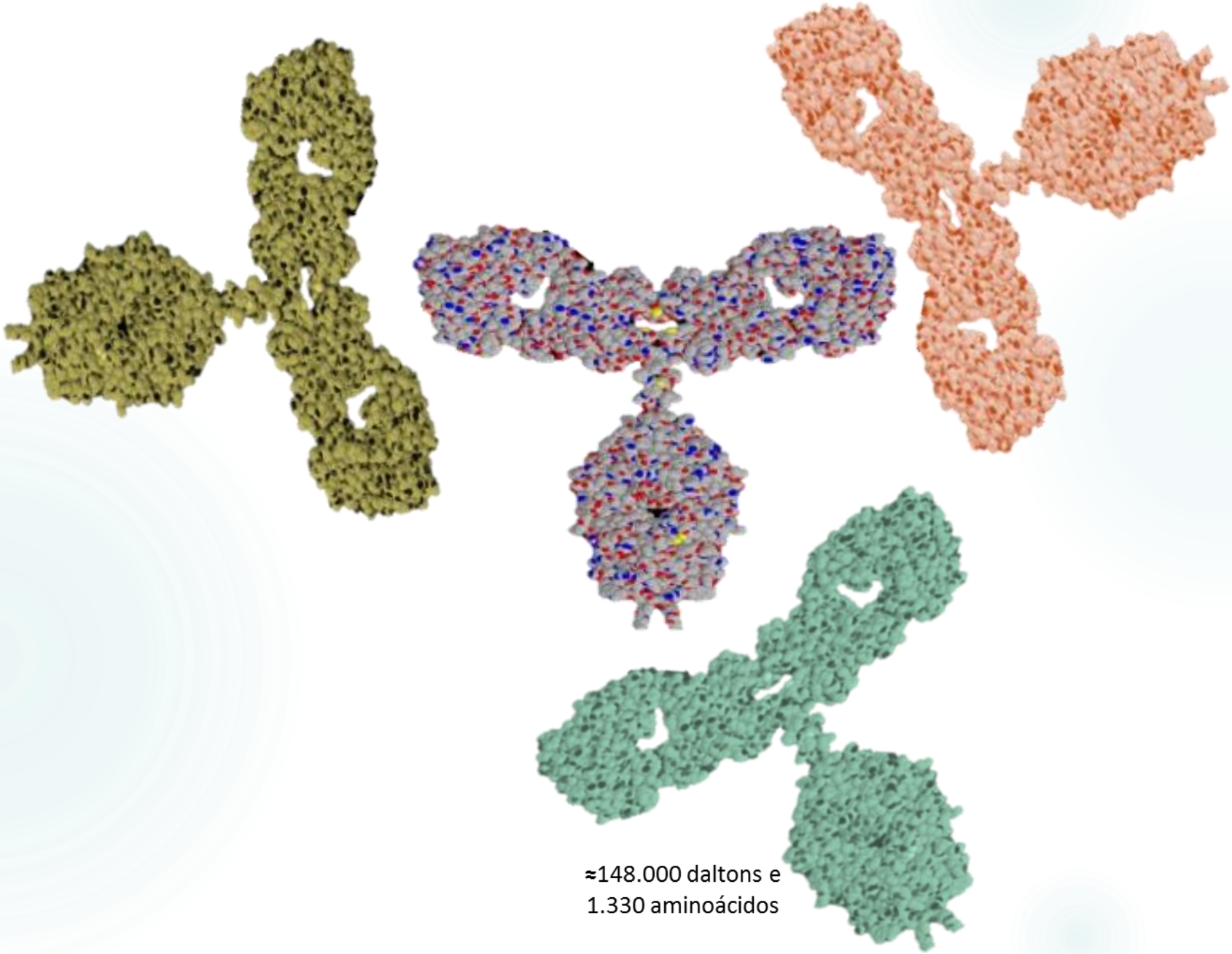
3)mas considerando a vid real







≈148.000 daltons e
1.330 aminoácidos



≈148.000 daltons e
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Consensus-based recommendations for the use of biosimilars to treat rheumatological diseases.

Table 1 Overarching principles (A–E) and consensus recommendations (1–8) for biosimilars

		Agreement* (%)	Level of evidencet	Grade of recomme
Overarching principles				
A.	Treatment of rheumatic diseases is based on a shared decision-making process between patients and their rheumatologists.	100	5	D
B.	The contextual aspects of the healthcare system should be taken into consideration when treatment decisions are made.	100	5	D
C.	A biosimilar, as approved by authorities in a highly regulated area, is neither better nor worse in efficacy and not inferior in safety to its bio-originator.	88	5	D
D.	Patients and healthcare providers should be informed about the nature of biosimilars, their approval process, and their safety and efficacy.	96	5	D
E.	Harmonised methods should be established to obtain reliable pharmacovigilance data, including traceability, about both biosimilars and bio-originators.	100	5	D

Kay et al. Ann Rheum Dis. 2017 Sep 2. pii: annrheumdis-2017-211937. doi: 10.1136/annrheumdis-2017-211937.

Consensus-based recommendations for the use of biosimilars to treat rheumatological diseases.

		Agreement* (%)	Level of evidencet	Grade of recomme
Consensus recommendations				
1.	The availability of biosimilars must significantly lower the cost of treating an individual patient and increase access to optimal therapy for all patients with rheumatic diseases.	100	5	D
2.	Approved biosimilars can be used to treat appropriate patients in the same way as their bio-originators.	100	1b	A
3.	As no clinically significant differences in immunogenicity between biosimilars and their bio-originators have been detected, antidrug antibodies to biosimilars need not be measured in clinical practice.	100	2b	B
4.	Relevant preclinical and phase I data on a biosimilar should be available when phase III data are published.	100	5	D
5.	Since the biosimilar is equivalent to the bio-originator in its physicochemical, functional and pharmacokinetic properties, confirmation of efficacy and safety in a single indication is sufficient for extrapolation to other diseases for which the bio-originator has been approved.	100	5	D
6.	Currently available evidence indicates that a single switch from a bio-originator to one of its biosimilars is safe and effective; there is no scientific rationale to expect that switching among biosimilars of the same bio-originator would result in a different clinical outcome but patient perspectives must be considered.	96	1b	A
7.	Multiple switching between biosimilars and their bio-originators or other biosimilars should be assessed in registries.	100	5	D
8.	No switch to or among biosimilars should be initiated without the prior awareness of the patient and the treating healthcare provider.	91	5	D

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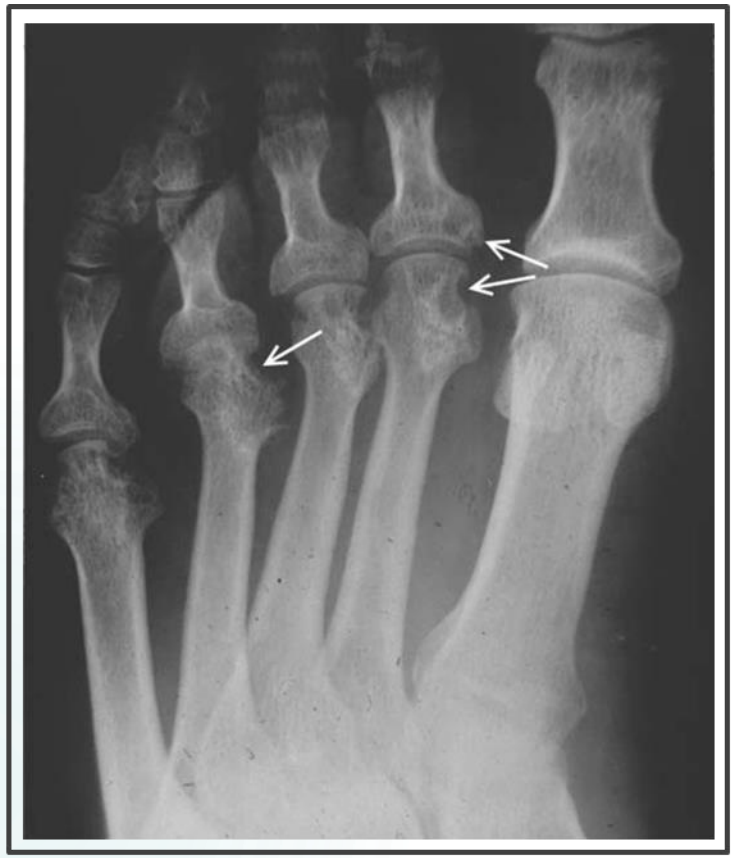

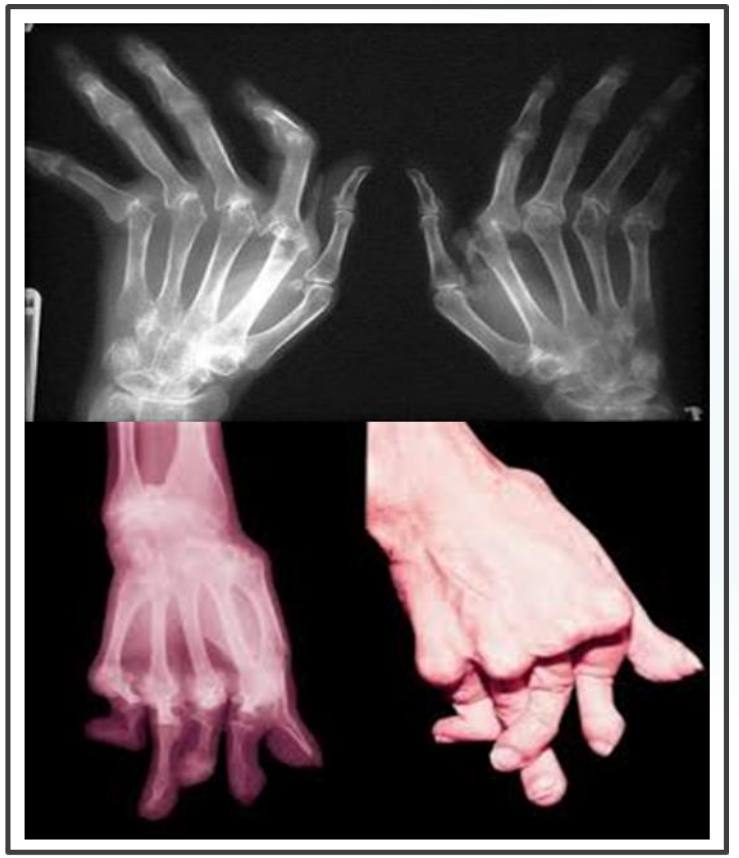

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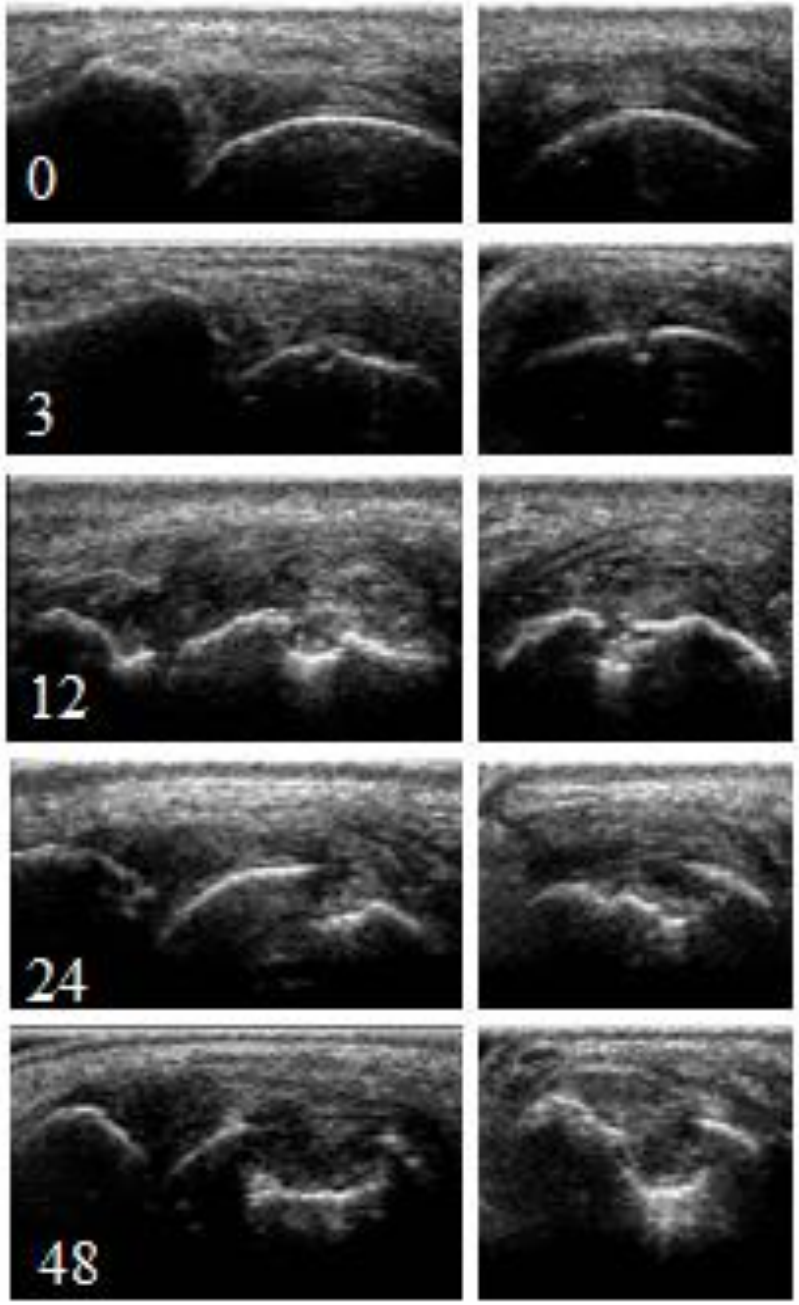
Vaz , Antonio Lopes. Artrite Reumatoide.2009 editora campus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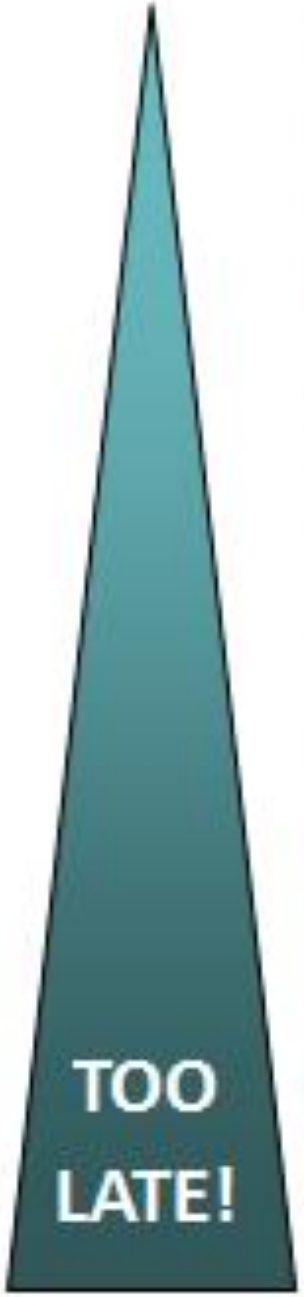
TOO
LATE!